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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,938	12/17/2003	Raul G. Barletta	801204-0003	8745

27910 7590 10/19/2006

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EXAMINER
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RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/738,938	<b>Applicant(s)</b> BARLETTA ET AL.	
	<b>Examiner</b> Delia M. Ramirez	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,5 and 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,6,11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/16/04, 10/18/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Application*

Claims 1-13 are pending.

Applicant's cancellation of claims 13-23 in a communication filed on 9/1/2006 is acknowledged.

Applicant's election with traverse of Group II, claims 3, 6, 11-12 drawn to a recombinant mycobacterium comprising the recombinant plasmid pBUN276, in a communication filed on 9/1/2006 is acknowledged.

Applicant traverses on the grounds that contrary to the Examiner's statement, plasmids pBUN250 and pBUN276 have related structures and each recombinant mycobacteria has the same class/subclass. Applicant also submits that while the recombinant mycobacteria may be distinct from each other, the Examiner has failed to show that examination of all claims or all claims directed to recombinant mycobacteria would place an undue burden on the Office.

Applicant's arguments have been fully considered but are not deemed persuasive to withdraw the restriction requirement. According to the specification, Table 1, pBUN250 contains the complete *ddl* gene from *M. smegmatis* whereas pBUN276 contains the *M. tuberculosis* gene. Thus, absent evidence to the contrary, each gene is presumed to have a different structure as they would have an unrelated nucleotide sequence. An examination of all the inventions previously presented would impose an undue burden on the Office since a comprehensive search of all the inventions would require a separate patent/non-patent literature search, and class/subclass search. In addition, while it is agreed that the recombinant mycobacteria was placed in the same class/subclass classification, a search of all the inventions directed to mycobacteria would place an undue burden on the Office since a comprehensive search of all the inventions would require a separate patent/non-patent literature search. While this search may be overlapping, it is not co-extensive as different keywords would be required. Publications

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describing vectors and microorganisms comprising the *ddl* gene from *M. smegmatis* do not have to disclose vectors and microorganisms comprising the *ddl* gene from *M. tuberculosis*.

The requirement is deemed proper and therefore is made FINAL.

Claims 1-2, 4-5, 7-10 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 3, 6, 11-12 are at issue and are being examined herein.

### ***Specification***

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See paragraph [062] page 22. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
2. The specification is objected to as containing blank spaces at locations which provide information regarding a biological deposit. See paragraph [094], page 37. Appropriate correction is required.

### ***Priority***

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/434,200 filed on 12/17/2002.

### ***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on 7/16/2004 and 10/18/2004 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

***Drawings***

5. The drawings submitted 12/17/2003 are objected to for the following reasons. The X-axis label on Figure 6 is missing letters. As submitted, it reads "Retention tim (min)". It should be amended to recite "Retention time (min)". Appropriate correction is required.

***Claim Rejections - 35 USC § 112, Second Paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 6, 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 3 (claims 6, 11-12 dependent thereon) is indefinite in the recitation of "Accession No. \_\_\_\_\_" as the claim lacks the number corresponding to the biological deposit recited. Correction is required.

9. Claim 6 is indefinite in the recitation of "plasmid pBUN276, said plasmid contained within the transformed mycobacterium strain of claim 3" as it is unclear how the term "said plasmid contained within the transformed mycobacterium strain of claim 3" further limits the plasmid. As written, it appears as if the claim excludes plasmid pBUN276 if present in a different microorganism. However, it is noted that the claim is directed to the plasmid, and absent evidence to the contrary, the structure of plasmid pBUN276 should remain the same regardless of the host containing it. For examination purposes, no patentable weight will be given to the term "said plasmid contained within the transformed mycobacterium strain of claim 3". Correction is required.

10. Claim 11 (claim 12 dependent thereon) is indefinite due to the recitation of "transformed microorganism comprising a host mycobacterium and the plasmid of claim 6" for the following reasons.

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As written, the claim requires a microorganism to comprise a mycobacterium. However, as known in the art, a mycobacterium is a microorganism. Thus, it is unclear as to how a microorganism can comprise another microorganism. For examination purposes, it will be assumed that the term reads "transformed microorganism comprising the plasmid of claim 6". Correction is required.

11. Claim 12 is indefinite in the recitation of "*M. smegmatis*, *M. tuberculosis*, ....and any genetic variants thereof" for the following reasons. The claim is indefinite because one of skill in the art cannot determine the scope of the Markush group recited (i.e., which species are encompassed). The term "genetic variant" as recited in the claims is deemed indefinite in view of the fact that the term can encompass unknown mycobacterial species which are outside the group of Mycobacterial species recited in the absence of a statement defining the level of genetic variation. For example, if undefined, a human can be considered a genetic variant of a microbe as humans evolved from an ancestral prokaryote through a series of genetic modifications. For examination purposes, no patentable weight will be given to the term "any genetic variants thereof". Correction is required.

***Claim Rejections - 35 USC § 112, First Paragraph***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 3, 6, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel vectors/microorganisms. Since the vectors/microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the

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specification or otherwise be readily available to the public. The vectors' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. 112 may be satisfied by a deposit of the vectors/microorganisms. The specification does not disclose a repeatable process to obtain the vectors/microorganisms and it is not apparent if the vectors' sequences are readily available to the public. Accordingly, it is deemed that a deposit of these vectors/microorganisms should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that Applicant has indicated that a deposit was made on page 34 of the specification. However, there is no indication in the specification as to public availability. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific vectors/microorganisms have been deposited under the Budapest Treaty and that the vectors/microorganisms will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- a. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- b. upon granting of the patent the vectors/microorganisms will be available to the public under the conditions specified in 37 CFR 1.808;
- c. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- d. the deposit will be replaced if it should ever become unviable.

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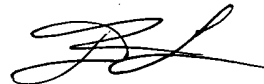
***Conclusion***

14. No claim is in condition for allowance.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
October 12, 2006